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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/743,260	03/05/2001	Amnon Sintov	1268-115	7810

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EXAMINER

PULLIAM, AMY E

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 12/18/2002

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/743,260

Applicant(s)

SINTOV ET AL.

Examiner

Amy E Pulliam

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-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 September 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-25 is/are pending in the application.
- 4a) Of the above claim(s) 26-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Receipt of Papers

Receipt is acknowledged of the Amendment A, received by the Office September 27, 2002.

Election/Restrictions

Newly submitted claims 26-35 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Applicant's originally filed claims were all composition claims. The above listed claims are method of use claims.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 26-35 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 11-25 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 8333243 to Fumiko *et al.*. Fumiko *et al.* disclose in their abstract a tablet which comprises fats and oils. Furthermore, the abstract teaches that in an example, Witepsol is used as the fat or oil substance.

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Additionally, the abstract teaches that the tablet is obtained by compression molding. Fumiko *et al.* also teach the presence of microcapsules, and the presence of an active agent. Fumiko *et al.* also teach the presence of excipients. Therefore, the abstract of Fumiko *et al.* reads on applicant's instant claims.

It is noted that the reference does not teach that the composition can be used in the manner instantly claimed, however, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.

Applicant's arguments have been fully considered but are not found to be persuasive. Applicant argues that the claimed product is made by compression or granulation, rather than molding. Applicant argues that this means the structure of the claimed product is different. The examiner appreciates applicant's arguments, however, they are not found to be persuasive. Applicant's instant claims are composition claims, not method of making claims. Therefore, the limitation in the claims directed to the method of making, does not render patentable distinction. Anticipating the examiner's response, applicant has argued that the claimed product is different than the prior art product, due to the different process of making. However, this distinction will only render patentable weight to a composition claim if the differences in the composition are actually recited in the claim language.

Applicant argues that the reference does not teach that the composition can be used in the same manner disclosed by applicant. This argument is not found persuasive, because applicant elected composition claims, rather than method of use claims, by original presentation.

Applicant further argues that the reference does not suggest that their tablets improve drug absorption, or permit higher drug content per tablet. However, when a composition is being claimed, it is not necessary that the prior art acknowledge each and every benefit of the composition. It is only necessary that the prior art teaches the same components in the composition.

Claims 11-14, and 16-25 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,219,563 to Douglas *et al.*. Douglas *et al.* teaches a tablet composition which comprises an active agent and Witespol. Douglas *et al.* teach that the composition is made by heating the composition and molding the composition into a tablet. Douglas *et al.* also teach that the formulation can take the form of capsules, granules, powders, tablets, or lozenges (c 3, l 21-22). Furthermore, the reference teaches that conventional carriers and excipients, such as lubricant and binders are acceptable in the formulation (c 3, l 28-48).

It is noted that the reference does not teach that the composition can be used in the manner instantly claimed, however, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.

Applicant's arguments have been fully considered but are not found to be persuasive. Applicant's arguments concerning this reference are all related to the method of making the composition. It is reiterated that compositions can not be differentiated by their methods of making, unless the methods result in materially different products, and these compositional differences are recited in the claims. However, the examiner would like to point applicant's attention to column 3, lines 44-46, where Douglas *et al.* state that the tablets may be obtained by compressing the granules. This is the same method disclosed by applicant.

Applicant also argues that the reference does not teach the intended use of the composition. However, as stated above, composition claims were elected by original presentation, and therefore, the method claims have been withdrawn from consideration.

Applicant further argues that the total weight of the reference tablet is 2.4 g, which would be unsuitable for oral formulations. This is completely contradictory to the teachings of the reference which clearly state that the composition is useful for oral administration (See abstract). For the above reasons, this rejection is maintained, and applied to the new claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fumiko *et al.*. Fumiko *et al.* disclose a fats and oils containing tablets comprising granules. Additionally, the abstract of Fumiko *et al.* teaches the inclusion of excipients. The abstract of Fumiko *et al.* does not specifically teach the inclusion of a surfactant. However, it is the position of the examiner that one of ordinary skill in the art would have been motivated to include a well known pharmaceutical excipient, such as a surfactant, into a tablet composition, such as that described by Fumiko *et al.*. Additionally, it is the position of the examiner that the main inventive concept behind applicant's invention is the use of Witespol in the composition. Fumiko *et al.* shows that Witespol has been previously been used in granular and tablet pharmaceutical formulations. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 11-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Douglas *et al.*. Douglas *et al.* is described above as teaching a tablet composition comprising a drug and Witespol. Douglas *et al.* do not teach the composition in granular form. However, Douglas *et al.* does teach that the composition of their invention can be used in tablet, granular, or suspension form (abstract). Therefore, it is the position of the examiner that one of ordinary skill in the art would have been motivated to use Witespol (an excipient used in the tablet composition) in a granular composition, with the same expected result. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

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Applicant's arguments have been fully considered but are not found to be persuasive for the reasons stated in the above discussions.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is 703-308-4710. The examiner can normally be reached on Mon-Thurs 7:30-5:00, Alternate Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone numbers for the

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organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

A. Pulliam
Patent Examiner
Art Unit 1615
December 10, 2002



CARLOS AZPURU
PRIMARY EXAMINER
GROUP 1500